Applicants:

Gary W. Cleary et al.

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his listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-6 (canceled)

Claim 7 (currently amended): The device of claim 6 in which A transdermal, transmucosal active delivery system comprising:

an ultra thin polymeric film member having a thickness of less than 0.002 inches;

a layer of adhesive coating at least a portion of a first side of said ultra thin film, whereby said layer of ultra thin film can be adhered to a dermal or mucosal layer;

a transdermally-effective active ingredient secured to said first side of said ultra thin film, wherein said transdermally-effective active ingredient is contained in an island member whose dimension are less extensive in scope then the dimensions of said ultra thin film, said island member comprising a backing member to which said transdermally-effective active ingredient is secured, said backing member being adhered to said ultra thin film layer by said first adhesive layer; and wherein said transdermally-effective active ingredient is incorporated into a layer of adhesive which is applied to said island backing member.

Claims 8-11 (canceled)

Claim 12 (currently amended): A transdermal-dermal, transmucosal-mucosal delivery system comprising:

a handle having a first adhesive coated on a first side thereof;

an ultra thin polymeric film with a thickness under 0.002 inches and having a first and a second side;

a second adhesive layer on the first side of said ultra thin film, the first adhesive of the handle being adhered to the second side of said ultra thin film, said handle at least partially extending beyond at least one edge of the said ultra thin film;

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a transdermally-effective pharmacologically active ingredient secured to said first side of said ultra thin film;

a release liner adhered to and covering said first side of said ultra thin film, including said second adhesive layer and said transdermally-effective active ingredient, said liner at least partially extending beyond at least one edge of said ultra thin film such that it also at least partially covers contacts at least a portion of said first adhesive layer on said handle;

wherein the second adhesive adheres more aggressively to skin or mucosa than said first adhesive adheres to said second side of said ultra thin film, whereby said handle can be removed from the second side of the ultra thin film once the first side of said ultra thin film is adhered to a patient's skin or mucosa.

Claim 13 (original): The transdermal-dermal, transmucosal-mucosal delivery system of claim 12, wherein said first side of said handle is entirely coated with the first adhesive.

Claim 14 (currently amended): The transdermal dermal, transmucosal mucosal delivery system of claim 13, wherein A transdermal-dermal, transmucosal-mucosal delivery system comprising:

a handle having a first adhesive coated on a first side thereof;
an ultra thin polymeric film with a thickness under 0.002 inches and having a first and a second side;

a second adhesive layer on the first side of said ultra thin film, the first adhesive of the handle being adhered to the second side of said ultra thin film, said handle at least partially extending beyond at least one edge of the said ultra thin film;
a transdermally-effective pharmacologically active ingredient secured to said first side of said ultra thin film;
a release liner adhered to and covering said first side of said ultra thin film, including said second adhesive layer and said transdermally-effective active ingredient, said liner at least partially extending beyond at least one edge of said ultra thin film such that it also at least

partially covers said first adhesive layer on said handle;

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wherein the second adhesive adheres more aggressively to skin or mucosa than said first adhesive adheres to said second side of said ultra thin film, whereby said handle can be removed from the second side of the ultra thin film once the first side of said ultra thin film is adhered to a patient's skin or mucosa, and wherein said first side of said handle is entirely coated with the first adhesive, said first adhesive comprises a pressure sensitive adhesive which does not adhere to said release liner, or to skin, or mucosa.

Claim 15 (original): The transdermal-dermal, transmucosal-mucosal delivery system of claim 13, wherein said first adhesive comprises a pressure sensitive adhesive which adheres less aggressively to said release liner, or to skin, or mucosa, then does said second adhesive.

Claim 16 (previously presented): The transdermal-dermal, transmucosal-mucosal delivery system of claim 12, wherein the ultra thin film has a thickness between about 0.0003 and about 0.0015 inches.

Claim 17 (original): The transdermal-dermal, transmucosal-mucosal delivery system of claim 12, wherein the first side of the second film is entirely coated with the second adhesive.

Claim 18 (original): The delivery system of claim 12 in which said release liner comprises two separate portions, a first portion covering a portion of said first side of said ultra thin film and a second portion covering the remainder of said first side of said ultra thin film;

each of said release liner portions including at least a tab portion extending beyond the perimeter of said handle, whereby a user can grasp one portion of said release liner by its said tab using one set of digits and can grasp the remainder of the delivery system using another set of digits, and then peel said first portion of said release liner away from said delivery system, and can thereafter grasp the exposed portion of the delivery system with one set of digits and grasp said tab of said second portion of said release liner with another set of digits and peel said second portion of said release liner away from the remainder of said delivery system.

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Claim 19 (original): The delivery system of claim 18 in which said first portion of said release liner covers at least that portion of said handle which extends beyond said ultra thin film, such that when said first portion of said release liner is peeled away, the extending portion of said handle can be grasped, without also grasping a portion of said ultra thin film.

Claim 20 (original): The transdermal-dermal, transmucosal-mucosal delivery system of claim 12, wherein the first and second adhesives are pressure sensitive adhesives.

Claim 21 (currently amended): The transdermal dermal, transmucosal mucosal delivery system of claim 12, wherein A transdermal-dermal, transmucosal-mucosal delivery system comprising:

a handle having a first adhesive coated on a first side thereof;
an ultra thin polymeric film with a thickness under 0.002 inches and having a first and a second side;
a second adhesive layer on the first side of said ultra thin film, the first adhesive of the handle being adhered to the second side of said ultra thin film, said handle at least partially extending beyond at least one edge of the said ultra thin film;
a transdermally-effective pharmacologically active ingredient secured to said first side of said ultra thin film;
a release liner adhered to and covering said first side of said ultra thin film, including said second adhesive layer and said transdermally-effective active ingredient, said liner at least partially extending beyond at least one edge of said ultra thin film such that it also at least

wherein the second adhesive adheres more aggressively to skin or mucosa than said first adhesive adheres to said second side of said ultra thin film, whereby said handle can be removed from the second side of the ultra thin film once the first side of said ultra thin film is adhered to a patient's skin or mucosa; and wherein said first adhesive comprises a pressure sensitive adhesive which does not adhere to said release liner, or to skin, or mucosa.

partially covers said first adhesive layer on said handle;

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Claim 22 (original): The transdermal-dermal, transmucosal-mucosal delivery system of claim 12, wherein said first adhesive comprises a pressure sensitive adhesive which adheres less aggressively to said release liner, or to skin, or mucosa, then does said second adhesive.

Claim 23 (original): The transdermal-dermal, transmucosal-mucosal delivery system of claim 22, wherein the second film thickness is between about 0.0003 and 0.0015 inches.

Claim 24 (original): The transdermal-dermal, transmucosal-mucosal delivery system of claim 23, wherein the first side of the second film is entirely coated with the second adhesive.

Claim 25 (currently amended): A transdermal-dermal, transmucosal-mucosal delivery system comprising:

a handle having a first adhesive coated on a first side thereof;

an ultra thin polymeric film with a thickness of less than 0.002 inches and having a first and a second side;

a second adhesive coated on the first side of said ultra thin film, the first adhesive of the handle being adhered to the second side of said ultra thin film, said handle at least partially extending beyond at least one edge of the said ultra thin film;

a transdermally-effective active ingredient contained in an island member whose dimensions are less extensive in scope than the dimensions of said ultra thin film;

said island member comprising a backing member to which said active ingredient is secured;

said backing member being adhered to said ultra thin film layer by said second adhesive layer;

a release liner adhered to and covering said first side of said ultra thin film, including said second adhesive layer and said transdermally-effective active ingredient, said liner at least partially extending beyond at least one edge of said ultra thin film such that it also at least partially covers contacts at least a portion of said first adhesive layer on said handle;

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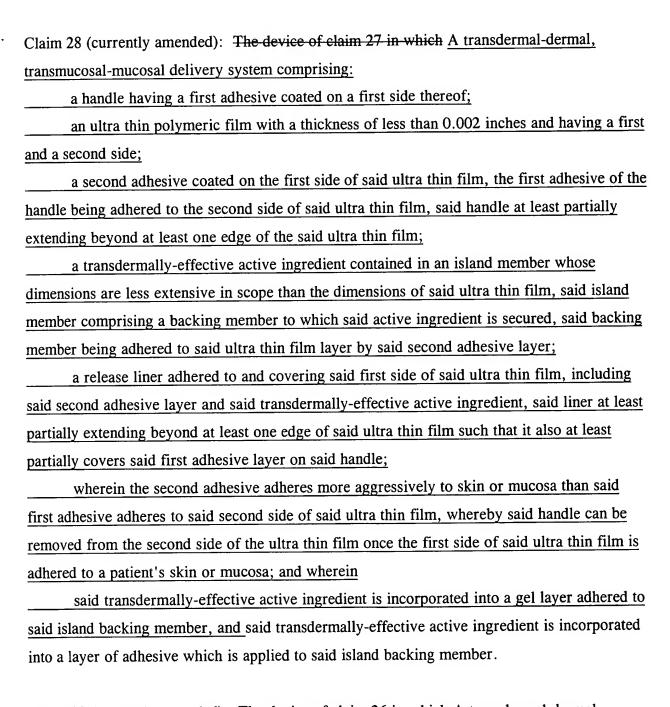
wherein the second adhesive adheres more aggressively to skin or mucosa than said first adhesive adheres to said second side of said ultra thin film, whereby said handle can be removed from the second side of the ultra thin film once the first side of said ultra thin film is adhered to a patient's skin or mucosa.

Claim 26 (currently amended): The device of claim 25 in which A transdermal-dermal, transmucosal-mucosal delivery system comprising: a handle having a first adhesive coated on a first side thereof; an ultra thin polymeric film with a thickness of less than 0.002 inches and having a first and a second side; a second adhesive coated on the first side of said ultra thin film, the first adhesive of the handle being adhered to the second side of said ultra thin film, said handle at least partially extending beyond at least one edge of the said ultra thin film; a transdermally-effective active ingredient contained in an island member whose dimensions are less extensive in scope than the dimensions of said ultra thin film, said island member comprising a backing member to which said active ingredient is secured, said backing member being adhered to said ultra thin film layer by said second adhesive layer; a release liner adhered to and covering said first side of said ultra thin film, including said second adhesive layer and said transdermally-effective active ingredient, said liner at least partially extending beyond at least one edge of said ultra thin film such that it also at least partially covers said first adhesive layer on said handle; wherein the second adhesive adheres more aggressively to skin or mucosa than said first adhesive adheres to said second side of said ultra thin film, whereby said handle can be removed from the second side of the ultra thin film once the first side of said ultra thin film is adhered to a patient's skin or mucosa; and wherein said transdermally-effective active ingredient is incorporated into a layer of adhesive which is applied to said island backing member.

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Claim 27 (previously presented): The device of claim 25 in which said transdermally-effective active ingredient is incorporated into a gel layer adhered to said island backing member.



Claim 29 (currently amended): The device of claim 26 in which A transdermal-dermal, transmucosal-mucosal delivery system comprising:

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a handle having a first adhesive coated on a first side thereof; an ultra thin polymeric film with a thickness of less than 0.002 inches and having a first and a second side; a second adhesive coated on the first side of said ultra thin film, the first adhesive of the handle being adhered to the second side of said ultra thin film, said handle at least partially extending beyond at least one edge of the said ultra thin film; a transdermally-effective active ingredient contained in an island member whose dimensions are less extensive in scope than the dimensions of said ultra thin film, said island member comprising a backing member to which said active ingredient is secured, said backing member being adhered to said ultra thin film layer by said second adhesive layer; a release liner adhered to and covering said first side of said ultra thin film, including said second adhesive layer and said transdermally-effective active ingredient, said liner at least partially extending beyond at least one edge of said ultra thin film such that it also at least partially covers said first adhesive layer on said handle; wherein the second adhesive adheres more aggressively to skin or mucosa than said first adhesive adheres to said second side of said ultra thin film, whereby said handle can be removed from the second side of the ultra thin film once the first side of said ultra thin film is adhered to a patient's skin or mucosa; and wherein said transdermally-effective active ingredient is incorporated into a layer of adhesive which is applied to said island backing member, and said transdermally-effective active ingredient is contained in a reservoir adhered to said island backing member.

Claim 30 (original): The transdermal-dermal, transmucosal-mucosal delivery system of claim 25, wherein said first side of said handle is entirely coated with the first adhesive.

Claim 31 (original): The transdermal-dermal, transmucosal-mucosal delivery system of claim 30, wherein said first adhesive comprises a pressure sensitive adhesive which does not adhere to said release liner, or to skin, or mucosa.

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Claim 32 (original): The transdermal-dermal, transmucosal-mucosal delivery system of claim 30, wherein said first adhesive comprises a pressure sensitive adhesive which adheres less aggressively to said release liner, or to skin, or mucosa, then does said second adhesive.

Claim 33 (original): The transdermal-dermal, transmucosal-mucosal delivery system of claim 25, wherein the first side of the second film is entirely coated with the second adhesive.

Claim 34 (original): The delivery system of claim 25 in which said release liner comprises two separate portions, a first portion covering a portion of said first side of said ultra thin film and a second portion covering the remainder of said first side of said ultra thin film;

each of said release liner portions including at least a tab portion extending beyond the perimeter of said handle, whereby a user can grasp one portion of said release liner by its said tab using one set of digits and can grasp the remainder of the delivery system using another set of digits, and then peel said first portion of said release liner away from said delivery system, and can thereafter grasp the exposed portion of the delivery system with one set of digits and grasp said tab of said second portion of said release liner with another set of digits and peel said second portion of said release liner away from the remainder of said delivery system.

Claim 35 (original): The delivery system of claim 34 in which said first portion of said release liner covers at least that portion of said handle which extends beyond said ultra thin film, such that when said first portion of said release liner is peeled away, the extending portion of said handle can be grasped, without also grasping a portion of said ultra thin film.

Claim 36 (original): The transdermal-dermal, transmucosal-mucosal delivery system of claim 25, wherein the first and second adhesives are pressure sensitive adhesives.

Claim 37 (currently amended): The transdermal-dermal, transmucosal-mucosal-delivery system of claim 25, wherein-A transdermal-dermal, transmucosal-mucosal delivery system comprising:

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a handle having a first adhesive coated on a first side thereof; an ultra thin polymeric film with a thickness of less than 0.002 inches and having a first and a second side; a second adhesive coated on the first side of said ultra thin film, the first adhesive of the handle being adhered to the second side of said ultra thin film, said handle at least partially extending beyond at least one edge of the said ultra thin film; a transdermally-effective active ingredient contained in an island member whose dimensions are less extensive in scope than the dimensions of said ultra thin film, said island member comprising a backing member to which said active ingredient is secured, said backing member being adhered to said ultra thin film layer by said second adhesive layer; a release liner adhered to and covering said first side of said ultra thin film, including said second adhesive layer and said transdermally-effective active ingredient, said liner at least partially extending beyond at least one edge of said ultra thin film such that it also at least partially covers said first adhesive layer on said handle; wherein the second adhesive adheres more aggressively to skin or mucosa than said first adhesive adheres to said second side of said ultra thin film, whereby said handle can be removed from the second side of the ultra thin film once the first side of said ultra thin film is adhered to a patient's skin or mucosa; and wherein said first adhesive comprises a pressure sensitive adhesive which does not adhere to said release liner, or to skin, or mucosa.

Claim 38 (original): The transdermal-dermal, transmucosal-mucosal delivery system of claim 25, wherein said first adhesive comprises a pressure sensitive adhesive which adheres less aggressively to said release liner, or to skin, or mucosa, then does said second adhesive.

Claim 39 (original): The transdermal-dermal, transmucosal-mucosal delivery system of claim 38, wherein the first side of the second film is entirely coated with the second adhesive.

Claim 40 (currently amended): A method of making a transdermal-dermal, transmucosal-mucosal delivery system comprising:

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providing a handle having a first adhesive coated on a first side thereof;

providing an ultra thin polymeric film with a thickness under 0.002 inches and having a first and a second side;

providing a second adhesive;

coating said second adhesive to the first side of said ultra thin film;

adhering the first adhesive of the handle to the second side of said ultra thin film, said handle at least partially extending beyond at least one edge of the said ultra thin film;

providing a transdermally-effective active ingredient secured to said first side of said ultra thin film;

providing a release liner adhered to and covering said first side of said ultra thin film, including said second adhesive and said transdermally-effective active ingredient, said liner at least partially extending beyond at least one edge of said ultra thin film such that it also at least partially covers contacts said first adhesive layer on said handle.